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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,670	03/28/2000	FREDERIC BONTE	00060	7942

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/508,670	Applicant(s) BONTE ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/11/2003, 7/25/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-92* is/are pending in the application.

4a) Of the above claim(s) *78-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-77 and 87-92* is/are rejected.

7)☒ Claim(s) *74-92* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July and August 2003 has been entered.

Claims 70-92 are pending

Election/Restrictions

Applicant has made an election of species set forth in Paper No. 12, filed on May 24, 2002. Accordingly, the continued examination of the pending claims is directed to the same species elected on May 24, 2002. Claims as pending are is directed to such species encompassing methods of improving cohesion between dermis and epidermis, comprising delivering to skin or hair a person in need thereof, a cosmetically effective amount of ellagic acid, a retinoid, and *pygeum africanum*.

Claims 70-77, 87-92 are directed to the elected species and are thus under consideration. Accordingly at this point, claims 78-86 are withdrawn from further consideration, because they are directed to the non-elected species.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims

are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims are 74-92. There are two claims numbered 74. The misnumbered claims 74-92 have been renumbered 75-93.

Applicant however is encouraged to check proper dependency of the claims and submit any corrections needed to properly define the scope of their claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 70-77, 87-92 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the disclosure lacks sufficient written description for claimed methods of improving dermis-epidermis cohesion comprising administering ellagic acid or ether derivatives thereof to a subject in need thereof.

The first paragraph of 25 USC 112 requires that the "specification shall contain a written description of the invention." This requirement is separate and distinct from the enablement requirement. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). Accordingly, "the essential goal of the description of the invention requirement is to clearly convey the information that an applicant has invented

the subject matter which is claimed." In re Barker, 559 F.2d 588, 592n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). The instant application fails to meet such requirements.

First, the only mention of improving the cohesion between dermis and the epidermis, using ellagic acid, is in page 3, lines 20-21 of the specification. There is no other reference in the specification setting forth the details pertaining to such methods to the extend clarifying, how the cohesiveness of the dermis-epidermis junction has improved, what is the improvement relative to, and what process do Applicants have in possession at the time of filing.

Second, the state of art concerning the cohesion between dermis and epidermis is not well established. There is no certainty whether cohesiveness of dermis and epidermis is a function of skin ageing or lack of collagen VII in all possible subjects encompassed by the instant claims. In fact, it is noted that the instant examples are neither exhaustive, nor do they define the claimed methods. There is no working example directing one of ordinary skill in the art to methods of improving the cohesiveness of the dermis and epidermis using ellagic acid, retinoids and *pygeum africanum*. Thus, there is no correlation between the exemplified demonstration of the activity of ellagic acid in increasing the proportion of collagen VII in a culture cell and the cohesion between dermis and epidermis layer using the claimed species. Subsequently, one skilled in the art cannot reasonably conclude that the applicants had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70-77, 83-85, 87-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation of the pending claims for "improving dermis-epidermis cohesion in a subject" appears ambiguous, as there is no quantitative or qualitative measure described in the specification to define such process. The specification fails to provided a meaning for this clinical endpoint. The term appears relative in nature without pointing out the basis of the improvement. In another word, what is the cohesion of dermis-epidermis being compared to for assessment of the claimed "improvement." Accordingly, as the clinical endpoint appears to be a virtual goal, there is no clear way of appraising the metes and bound of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 70-77, 87-90, 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Arima et al US Patent 5,073,545 ("Arima") (PTO-892, Paper No. 5).

Arima discloses preparations for external application containing ellagic acid in an amount of about 0.001% to 20%, an amino acid and other suitable topical excipients including magnesium oxide, zinc compounds, citric acid, vitamins such as vitamin E or A, and various herbal extracts (see abstract, claims 1-9; col 11-12; col 5, lines 1-67

Thus, Arima meets the limitations of the compositions used for the instant cosmetic care methods.

Arima then claims methods of administering his compositions to human skin. (see col 13, lines 15-39). Applicant is reminded that in process claims, a recitation of the intended use does not impart patentability if the intended use does not result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Arima discloses topical administration of his compositions, Arima's patent inherently anticipates the functional limitations of the instant claims, because it meets all the manipulative steps of the claimed methods.

Applicant is also informed that the recitation of "improving dermis-epidermis cohesion in a subject in need thereof" is inherent to the process of applying an ellagic acid containing composition to living individuals. Examiner takes such position because corrosion of dermis-epidermis layer is a function of aging an subject to all living human beings. Therefore, applying ellagic acid to any subject inherently encompasses the "improving of dermis-epidermis cohesion in subjects in need thereof," because any aging individual would be inherently in need of such treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 70-77, 87-92 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Arima, in view of Soler et al US Patent 6,113,926 ("Soler") (PTO-892, Paper No. 5), Seguin et al US Patent 4,549,990 ("Seguin") (PTO-892, Paper No. 5) and Bonte US Patent 6,004,568.

Arima's teachings are discussed above. Arima further indicates that various suitable ingredients such as vitamin A (a reitinoid) and a suitable plant powder or extract may be added to their compositions for their desired therapeutic effects (see col 5, lines 1-5 and 60-65; col 6, lines 1-11). Arima fails to employ 5-alpha reductase inhibitors from extracts of *pygeum africanum.*

Solar teaches the use of African plums, *pygeum africanum*, in topical cosmetic and pharmaceutical compositions combined with various topical excipients, vitamins, and active agents (see abstract, col 3-4, col 6, lines 40-66). Solar indicates the use of African plums for various utilities including skin care associated with aging or acne (see col 1, lines 5-19; col 6, lines 21-42). Solar does not teach the combination of ellagic acid and *pygenum africanum.*

Seguin is solely use to show that African plum otherwise known as *pygenum africanum*, are readily prepared in powder and extract forms in combination with other vitamins or excipients in the area of cosmetic and pharmaceutical preparations. (see abstract; col 3, lines 55-59; col 4, lines 30-69).

Bonte also provides the use of topical extract compositions that are useful for improving collegan synthesis and improving dermal epidermal cohesion (see col 3, lines 1-55). Bonte's composition comprises extracts of *Berthollelia excelsa* which contain ellagotannins that are within the scope of the instantly claimed ellagic acids. (see abstract, col 4, lines 55-60). Bonte further provides for the use of suitable additives combined with herbal extaracts can promote the health of aging skin. (see col 5, lines 45-col6, line66).

Accordingly, absence of showing unexpected results, it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069(CCPA) 1980.

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to add *pygeum africanum* extract of Soler to the external compositions of Arima, because as suggested by Arima itself, and taught by Soler and Seguin, the ordinary artisan would have reasonably expected to improve the therapeutic benefits of Arima's compositions by adding a suitable herbal extract such as *pygeum africanum* which includes the 5 alpha reductase inhibitor of claim 91.

Further, as provided in Bonte's employing topical compositions containing ellagotannins, such as the ellagic acid of Arima, in combination with suitable additives and herbal extracts described in Soler and Sequin would have provided reasonable expectation of success in improving the cohesion of dermis-epidermis layers in patients in need of increasing the synthesis of collagen VII (eg. aging skin), because Bonte shows that such compounds are reduce wrinkle formation in aging subjects.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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